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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,548	05/29/2001	Gunnar Grue-Sorensen	P 277978	2538
2292	7590	02/11/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,548	Applicant(s) GRUE-SORENSEN ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10-15 and 21-42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-15 and 21-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 8, 10-15 and 21-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims as amended recite "with the proviso that said osteoporosis and related bone conditions are not caused by hyperparathyroidism". Said language does not find support in the present specification, including the amendment dated November 19, 2004 because the present specification lacks description of the claimed treatment method excluding osteoporosis and related bone conditions that are caused by hyperparathyroidism. According to the present specification, including the amendment dated November 19, 2004, the claimed compounds, which were disclosed in WO 91/15475, are useful in treatment of hyperparathyroidism. Said recitation does

not provide support for the exclusion of osteoporosis and related bone conditions caused by hyperparathyroidism.

Claim Rejections - 35 USC § 102

4. The rejections of claims 1-6, 8, 10-15, 21 and 22 under 35 USC 102(b) over Calverley et al. (WO 91/15475 or '629) are withdrawn based on the amendment to the instant claims.

Claim Rejections - 35 USC § 103

5. The rejections of claims 1-6, 8, 10-15, 21 and 22 under 35 USC 103(a) over Calverley et al. (WO 91/15475 or '629) are withdrawn based on the amendment to the instant claims.

Response to Arguments

6. Applicant argues (a) the references fail to disclose or describe the use of the disclosed compounds for the treatment of osteoporosis or related bone conditions; (b) the examiner assumes hyperparathyroidism is equivalent to osteoporosis and related bone conditions or that it would necessarily result to said conditions; (c) osteoporosis may be caused by other completely independent conditions and (d) at best, the additional publications which mention both hyperparathyroidism and osteoporosis are evidence that it might have been "obvious to try" to experiment in order to determine if

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the claimed compounds might be useful against osteoporosis. Applicant's argument was considered but not persuasive for the following reasons.

For the record, the examiner (a) does not assume that hyperparathyroidism is equivalent to osteoporosis and (b) is aware of the fact that there are other underlining causes of osteoporosis.

The instant claims recite "osteoporosis and related bone conditions" and are not limited to osteoporosis. As stated in the previous Office Action, it is recognized in the art that "osteoporosis, osteomalacia and hyperparathyroidism" are related bone disorders. The present specification discloses osteoporosis and osteomalacia as related bone conditions (see page 2, lines 6-13 of the present specification). If osteomalacia and osteoporosis are related bone conditions as disclosed by the present specification, than, it follows that hyperparathyroidism is included in the disorders encompassed by the phrase "related bone conditions" as recited by the instant claims because the art recognizes all three conditions as related bone disorders. The examiner fails to see how said teaching in the art is evidence of "obvious to try" when the present specification set forth "osteomalacia" as taught by the art as a condition encompassed by the phrase "related bone conditions".

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

February 10, 2005